30 May 2024
EMA/236201/2024
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): asciminib

Procedure No. EMEA/H/C/PSUSA/00011008/202310

Period covered by the PSUR: 29 April 2023 to 28 October 2023

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for asciminib, the scientific conclusions of the PRAC are as follows:

In view of available data on pancytopenia from clinical trial(s) and spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between asciminib and pancytopenia is at least a reasonable possibility. The PRAC concluded that the product information of products containing asciminib should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for asciminib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing asciminib is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.